IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF OKLAHOMA

(1) THE PONCA TRIBE OF INDIANS OF OKLAHOMA,

Plaintiff,

v.

(1) PURDUE PHARMA L.P.,
(2) PURDUE PHARMA INC.,
(3) THE PURDUE FREDERICK COMPANY,
(4) CEPHALON, INC.,
(5) TEVA PHARMACEUTICAL INDUSTRIES, LTD.,
(6) TEVA PHARMACEUTICALS USA, INC.,
(7) JANSSEN PHARMACEUTICALS, INC.,
(8) JOHNSON & JOHNSON,
(9) ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.,
(10) PD-RX PHARMACEUTICALS, INC.,
(11) JANSSEN PHARMACEUTICA, INC.,
(12) ENDO HEALTH SOLUTIONS INC.,
(13) ENDO PHARMACEUTICALS INC.,
(14) ALLERGAN PLC,
(15) ACTAVIS PLC,
(16) PHYSICIANS TOTAL CARE, INC.
(17) WATSON PHARMACEUTICALS, INC.,
(18) WATSON LABORATORIES, INC.,
(19) ACTAVIS PHARMA, INC.,
(20) WATSON PHARMA, INC.,
(21) ACTAVIS LLC,
(22) MALLINCKRODT PLC;
(23) MALLINCKRODT LLC;
(24) MCKESSON CORPORATION,
(25) CARDINAL HEALTH, INC.,
(26) AMERISOURCEBERGEN CORPORATION,

Defendants.

Case No. CIV-18-221-M

COMPLAINT

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COMPLAINT

I. INTRODUCTION

1. The opioid epidemic is a preventable tragedy occurring across the United States, but especially throughout Indian country. The epidemic of prescription opioid dependence has caused Plaintiff The Ponca Tribe of Indians of Oklahoma (hereinafter, "Ponca Tribe") to suffer substantial losses of social services resources, economic losses, and damages to the health and welfare of the Ponca people.

2. The Ponca Tribe brings this action in its own governmental capacity and under its *parens patriae* capacity to protect the health, safety, and welfare of all members of the Ponca Tribe.

3. Opioids are highly addictive and, traditionally, medical professionals prescribed them in limited circumstances to patients with cancer, terminal illnesses, or acute short-term pain. These limited uses, however, for which medical professionals prescribed opioids undermined Defendants' ability to maximize profits. Thus, Defendants sought to maximize their profits by selling more opioids. Defendants pursued, and indeed accomplished this goal, by expanding the market beyond the limited circumstances of medically necessary opioid use and successfully convinced medical professionals to prescribe opioids to a broader range of patients for longer periods of time.

4. Defendants chose to falsely downplay the risk of opioid addiction and overstate the efficacy of opioids for more wide-ranging conditions, including chronic non-cancer pain, in a willful effort to maximize their profits at the expense of human life. Over several years, Defendants implemented unprecedented and large-scale marketing

campaigns that misrepresented the risks of addiction from their opioids and pushed unsubstantiated benefits. Defendants were extremely successful in increasing the sales of opioids. For example, sales of OxyContin rose from roughly $48 million in 1996 to roughly $3 billion by 2009.

5. This epidemic has been growing for years and the effects of this crisis have only been exacerbated by Defendants' efforts to conceal and minimize the risks of opioid addiction.

6. The Ponca Tribe has seen its healthcare services overwhelmed and its costs to provide a wide range of social services, from child welfare to behavioral health, sky rocket. The result has been that virtually every tribal member has been adversely impacted by the opioid epidemic.

7. These costs could have been—and should have been—prevented by the opioid industrial complex. The prescription drug industry is required by statutes and regulations to secure and monitor opioids at every step in the stream of commerce, thereby protecting opioids from theft, misuse, and diversion. The industry is required to implement and follow processes to alert it to "red flags" that stop suspicious or unusual orders by pharmacies, doctors, clinics, or patients.

8. Instead of acting with reasonable care and in compliance with their legal duties, the Defendants intentionally saturated communities with opioids and pocketed billions of dollars in the process.

9. Defendants also flooded the market with false declarations designed to convince doctors, patients, and government entities that prescription opioids posed a low risk of addiction. Those claims were false.[1] And Defendants knew it.

10. Defendants' actions directly and foreseeably caused damages to the Ponca Tribe, including but not limited to, actual costs, the loss of opportunity, or diversion of: medical and therapeutic care, costs for social services for those suffering from opioid addiction, overdose, or death; counseling, treatment and rehabilitation services; treatment of infants born with opioid-related medical conditions; welfare and foster care for children whose parents suffer from opioid-related disability or incapacitation; and law enforcement and public safety relating to the opioid epidemic within the tribal communities. The Ponca Tribe has also suffered substantial damages due to the lost productivity of tribal members, increased administrative costs, and the lost opportunity for growth and self-determination. These damages have been suffered and continue to be suffered directly by the Ponca Tribe.

11. The Ponca Tribe seeks the abatement of the continuing epidemic created by Defendants' wrongful and/or unlawful conduct.

[1] *See* Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, available at http://turnthetiderx.org/ (last accessed December 18, 2017).

II. THE PARTIES

A. Plaintiff

12. The Ponca Tribe is a sovereign Indian Nation and a federally recognized Indian tribe. The citizens of the Ponca Tribe reside principally on their territory or "reservation" south of Ponca City. The headquarters of the Ponca Tribe are near White Eagle, Oklahoma. The Ponca Tribe exercises inherent and constitutional governmental authority on behalf of the Tribe itself and its members. The Ponca Tribe brings this action by the authority of the Business Committee of the Ponca Tribe, the sole government of the Ponca Tribe. The Ponca Tribe brings this action on its own behalf and on behalf of its members and citizens.

B. Pharmaceutical Defendants

13. The Pharmaceutical Defendants are defined below. At all relevant times, the Pharmaceutical Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of prescription opioid drugs. The Pharmaceutical Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

14. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut, and THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (Purdue

Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company are referred to collectively as "Purdue").

15. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the U.S., including within the Ponca Tribe's borders. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers). Purdue has registered with the Oklahoma Board of Pharmacy to do business in Oklahoma.

16. CEPHALON, INC. is a Delaware corporation with its principal place in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a wholly owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon, Inc. in October 2011.

17. Cephalon, Inc. manufactures, promotes, sells and distributes opioids such as Actiq and Fentora in the U.S., including within the Ponca Tribe's borders. The FDA approved Actiq and Fentora only for the management of breakthrough cancer pain in patients who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. In 2008, Cephalon pled guilty to a criminal violation of the Federal Food,

Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.

18. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon- branded products through its "specialty medicines" division. The FDA approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in Oklahoma, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva Ltd. has directed Cephalon, Inc. to disclose that it is a wholly owned subsidiary of Teva Ltd. on prescription savings cards distributed in Oklahoma, indicating Teva Ltd. would be responsible for covering certain co-pay costs. All of Cephalon's promotional websites, including those for Actiq and Fentora, prominently display Teva Ltd.'s logo. Teva Ltd.'s financial reports list Cephalon's and Teva's USA's sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales." Through interrelated operations like these, Teva Ltd. operates in Oklahoma and the rest of the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those

companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. (Teva Pharmaceuticals Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to collectively as "Cephalon"). Cephalon has registered with the Oklahoma Board of Pharmacy to do business in Oklahoma.

19. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON ("J&J"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. ORTHO-MCNEIL- JANSSEN PHARMACEUTICALS, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA, INC., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to collectively as "Janssen"). Upon information and belief, J&J controls the sale and development of Janssen Pharmaceutical's products and corresponds with the FDA regarding Janssen's products.

20. Janssen manufactures, promotes, sells, and distributes drugs in the U.S., including in Oklahoma, including the opioid Duragesic (fentanyl). Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together,

Nucynta and Nucynta ER accounted for $172 million in sales in 2014. Janssen has registered with the Oklahoma Board of Pharmacy to do business in Oklahoma.

21. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to collectively as "Endo").

22. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S., including in Oklahoma. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S., including in Oklahoma, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. Endo has registered with the Oklahoma Board of Pharmacy to do business in Oklahoma.

23. ALLERGAN PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired Allergan plc in March 2015. Before that, WATSON PHARMACEUTICALS, INC. acquired Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis plc in October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly owned subsidiary of Allergan plc (f/k/a Actavis, Inc., f/k/a Watson

Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey, and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Allergan plc, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. (Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to collectively as "Actavis").

24. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the U.S., including in Oklahoma. Actavis has registered with the Oklahoma Board of Pharmacy to do business in Oklahoma.

25. MALLINCKRODT, PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. MALLINCKRODT, LLC, is a limited liability company organized and existing under the laws of the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinkrodt, plc. Mallinckrodt, plc and Mallinckrodt, LLC are collectively referred to as "Mallinckrodt."

26. Mallinckrodt manufactures, markets, and sells drugs in the United States including generic oxycodone, of which it is one of the largest manufacturers. In July 2017,

Mallinckrodt agreed to pay $35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances. Mallinckrodt has registered with the Oklahoma Board of Pharmacy to do business in Oklahoma.

27. Collectively, Purdue, Cephalon, Janssen, Endo, Actavis and Mallinckrodt are the "Pharmaceutical Defendants".

C. Distributor Defendants

28. CARDINAL HEALTH, INC. ("Cardinal") is a publicly traded company incorporated under the laws of Ohio and with a principal place of business in Ohio. Cardinal distributes prescription opioids to providers and retailers, including in Oklahoma. Cardinal is registered to do business and receive service of process in Oklahoma. Cardinal is also registered with the Oklahoma Department of Health as a wholesale prescription drug distributor in Oklahoma.

29. AMERISOURCEBERGEN CORPORATION ("AmerisourceBergen") is a publicly traded company incorporated under the laws of Delaware and with a principal place of business in Pennsylvania. AmerisourceBergen distributes prescription opioids to providers and retailers, including in Oklahoma. AmerisourceBergen is registered to do business and receive service of process in Oklahoma. AmerisourceBergen is also registered with the Oklahoma Department of Health as a wholesale prescription drug distributor in Oklahoma.

30. MCKESSON CORPORATION ("McKesson") is a publicly traded company incorporated under the laws of Delaware and with a principal place of business in San

Francisco, California. McKesson distributes prescription opioids to providers and retailers, including in Oklahoma. McKesson is registered to do business and receive service of process in Oklahoma. McKesson is also registered with the Oklahoma Department of Health as a wholesale prescription drug distributor in Oklahoma.

31. PD-RX PHARMACEUTICALS, INC. ("PD-Rx") is a corporation organized and existing under the laws of the State of Oklahoma, with its principal place of business in Oklahoma City, duly authorized to transact business in the state of Oklahoma. PD-Rx is a packager and wholesale distributor of pharmaceuticals. PD-Rx receives large quantities of pharmaceuticals from pharmaceutical manufacturers and then repackages those pharmaceuticals into smaller packages, pursuant to the instructions of its customers, i.e. hospitals, government agencies, pharmacies, and treating physicians.

32. PHYSICIANS TOTAL CARE, INC. ("PTC") is a corporation organized and existing under the laws of the State of Oklahoma, with its principal place of business in the city of Tulsa, Oklahoma, duly authorized to transact business in the state of Oklahoma. PTC is a packager and wholesale distributor of pharmaceuticals. PTC receives large quantities of pharmaceuticals from pharmaceutical manufacturers and then repackages those pharmaceuticals into smaller packages, pursuant to the instructions of its customers, i.e. hospitals, government agencies, pharmacies, and treating physicians.

33. Collectively, Cardinal, AmerisourceBergen, McKesson, PD-Rx and PTC are the "Distributor Defendants".

34. The data which reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database. See

Madel v. U.S. D.O.J., 784 F.3d 448, 451 (8th Cir. 2015). Neither the DEA nor the wholesale distributors will voluntarily disclose the data necessary to identify with specificity the transactions which will form the evidentiary basis for the claims asserted herein. See id. at 452-53. Collectively, AmerisourceBergen, Cardinal, and McKesson dominate 85% of the market share for the distribution of prescription opioids. The "Big 3" are Fortune 500 corporations listed on the New York Stock Exchange whose principal business is the nationwide wholesale distribution of prescription drugs. *See* Fed. Trade Comm'n v. Cardinal Health, Inc., 12 F. Supp. 2d 34, 37 (D.D.C. 1998) (describing Cardinal, McKesson, and AmerisourceBergen predecessors). Each has been investigated and/or fined by the DEA for the failure to report suspicious orders. The Ponca Tribe has reason to believe each has engaged in unlawful conduct, which resulted in the diversion of prescription opioids into the Ponca Tribe's jurisdiction and community. The Ponca Tribe names each of the "Big 3" herein as defendants and places the industry on notice that the Ponca Tribe is acting to abate the public nuisance plaguing its community. The Ponca Tribe will request expedited discovery pursuant to Rule 26(d) of the Federal Rules of Civil Procedure to secure the data necessary to reveal and/or confirm the identities of the wholesale distributors, including data from the ARCOS database.

III. JURISDICTION AND VENUE

35. This Court has subject-matter jurisdiction under 28 U.S.C. § 1331 because this action presents a federal question. This Court has supplemental jurisdiction over the state-law causes of action under 28 U.S.C. § 1367 because the state-law claims are part of the same case or controversy.

36. This Court has personal jurisdiction over all Defendants because all Defendants have substantial contacts and business relationships with the State of Oklahoma, including consenting to be sued in Oklahoma by registering an agent for service of process and/or obtaining a distributor license and have purposefully availed themselves of business opportunities within the State of Oklahoma, including by marketing, distributing, or selling prescription opioids within the State of Oklahoma and within the Ponca Tribe's jurisdictional boundaries.

37. This Court also has personal jurisdiction over all of the defendants under 18 U.S.C. § 1965(b). This Court may exercise nationwide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring all members of the nationwide RICO enterprise before the court in a single trial. See, e.g., Iron Workers Local Union No. 17 Insurance Fund v. Philip Morris Inc., 23 F. Supp. 2d 796 (1998).

38. Venue is proper in this Court under 28 U.S.C. § 1391(b) and 18 U.S.C. § 1965 because a substantial part of the events or omissions giving rise to this action occurred in this judicial district and because all defendants are subject to this Court's exercise of personal jurisdiction.

IV. FACTUAL BACKGROUND

A. Overview of the Opioid Epidemic

39. Historically, opioids were considered too addictive and debilitating to be part of a long-term pain management regimen for chronic pain. Prior to the 1990s, the medical

profession adhered to the standard that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or end-of-life care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time, and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, medical professionals generally did not prescribe opioids for chronic pain.

40. Moreover, opioids also tend to induce tolerance, whereby a person who uses opioids repeatedly over time no longer responds to the drug as strongly as before, thus requiring a higher dose to achieve the same effect. This tolerance contributes to the high risk of overdose during a relapse.

41. As described herein, Defendants engaged in conduct that directly caused medical professionals to unwittingly prescribe long term and increased amounts of opioids. Defendants did so to take advantage of a much larger and lucrative market for chronic pain patients.

42. As a result of Defendants' wrongful conduct, prescription opioids have become widely prescribed. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.[2] From 1999 to 2013, the amount of prescription painkillers prescribed and

[2] Katherine M. Keyes et al., *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, 104 Am. J. Pub. Health e52 (2014).

sold in the United States nearly quadrupled. Yet, there had not been an overall change in the amount of pain reported by patients.

43. By 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention declared prescription painkiller overdoses to be at epidemic levels. The press release noted:

> a. The death toll from overdoses of prescription painkillers has more than tripled in the past decade.
>
> b. More than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin) and oxymorphone (Opana).
>
> c. Overdoses involving prescription painkillers are at epidemic levels and now kill more Americans than heroin and cocaine combined.
>
> d. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older—a total of 12 million people—reported using prescription painkillers non-medically, according to the National Survey on Drug Use and Health. Based on the data from the Drug Enforcement Administration, sales of these drugs to pharmacies and health care providers have increased by more than 300 percent since 1999.
>
> e. Prescription drug abuse is a silent epidemic that is stealing thousands of lives and tearing apart communities and families across America.
>
> f. Almost 5,500 people start to misuse prescription painkillers every day.[3]

[3] *See* Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

44. Many Americans, including members of the Ponca Tribe, are now addicted to prescription opioids and the number of deaths due to prescription opioid overdose has reached epidemic levels. In 2016, drug overdoses killed roughly 64,000 people in the United States, an increase of more than 22 percent over the 52,404 drug deaths recorded the previous year.[4] The President of the United States has declared the opioid epidemic a public health emergency.

45. The National Institute on Drug Abuse identifies addiction to opioids as "a serious national crisis that affects public health as well as social and economic welfare."[5] The economic burden of prescription opioid misuse alone is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment and criminal justice expenditures.[6]

46. Deaths from prescription opioids have quadrupled in the past 20 years and treatment admission and emergency room visits related to the abuse of opioids for non-medical use have also dramatically increased.

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[4] *See* Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Provisional Counts of Drug Overdose Deaths, (August 8, 2016), https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf.

[5] Opioid Crisis, NIH, National Institute on Drug Abuse (available at https://www.drugabuse.gov/drugs- abuse/opioids/opioid-crisis, last visited Sept. 19, 2017) ("Opioid Crisis, NIH") (citing at note 1 Rudd RA, Seth P, David F, Scholl L, Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015, *MMWR MORB MORTAL WKLY REP*. 2016;65, doi:10.15585/mmwr.mm655051e1).

[6] *Id.* (citing at note 2 Florence CS, Zhou C, Luo F, Xu L, The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013, *MED CARE* 2016;54(10):901-906, doi:10.1097/MLR.0000000000000625).

47. The increases in opioid deaths and addiction treatments are directly related to the prescribing practices created by Defendants. According to the CDC[7], opioid deaths and treatment admissions are tied to opioid sales.

48. The epidemic of prescription opioid addiction is devastating families and communities across the country. 8 Meanwhile, the manufacturers and distributors of prescription opioids extract billions of dollars of revenue from the addicted public, while governmental entities experience tens of millions of dollars of injury caused by the reasonably foreseeable consequences of Defendants' conduct.

49. The prescription opioid Pharmaceutical and Distributor Defendants have continued their wrongful, intentional and unlawful conduct, despite their knowledge that such conduct is causing and continuing to cause the opioid epidemic.

B. Overview of Indian Country Opioid Epidemic

50. Indian country has been ravaged by the opioid epidemic as a result of Defendants' deceptive marketing of opioids. Oklahoma is home to numerous Indian tribes and is one of the leading states in prescription painkiller sales per capita, with 128 painkiller prescriptions dispensed per 100 people in 2012. Drug overdose deaths in Oklahoma increased eightfold from 1999 to 2012, surpassing car crash deaths in 2009. In 2012,

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[7] U.S. Dep't of Health & Human Servs., *Addressing Prescription Drug Abuse in the United States*, available at https://www.cdc.gov/drugoverdose/pdf/hhs_prescription_drug_abuse_report_09.2013.p df (last accessed December 29, 2017).

[8] *See* Presidential Memorandum – Addressing Prescription Drug Abuse and Heroin Use, 2015 Daily Comp. Pres. Doc. 743 (Oct. 21, 2015), https://www.gpo.gov/fdsys/pkg/DCPD-201500743/pdf/DCPD-201500743.pdf.

Oklahoma had the fifth-highest unintentional poisoning death rate and prescription opioids contributed to the majority of these deaths.

51. In 2014, Oklahoma's unintentional poisoning rate was 107% higher than the national rate. Oklahoma had the 10th highest drug overdose death rate in the nation in 2014. Opioids are the most common class of drug involved in unintentional overdose deaths in Oklahoma.

52. In 2015, 823 fatal drug overdoses occurred in Oklahoma, an almost 140% increase over 2001, with opioids contributing to the largest number of these deaths. As of 2015, there were more prescription drug overdose deaths each year in Oklahoma than overdose deaths from alcohol and all illegal drugs combined.

53. In Oklahoma, more overdose deaths involved hydrocodone or oxycodone than methamphetamines, heroin, and cocaine combined.

54. According to 2016 statistics, Oklahoma ranks number one in the nation in milligrams of opioids distributed per adult resident with approximately 877 milligrams of opioids distributed per adult resident.

55. A National Survey on Drug Use and Health revealed Oklahoma leads the nation in non-medical use of painkillers, with nearly 5% of the population aged 12 and older abusing or misusing painkillers.

56. Prescription opioid abuse disproportionately impacts Indian communities. The CDC reported in 2012 that 1 in 10 American Indians/Native Americans (over the age

of 12) used prescription pain medicine for nonprescription purposes, compared with 1 in 20 whites and 1 in 30 African- Americans.[9]

57. The Defendants' saturation of communities with prescription opioids has created accessibility and availability of prescription opioids which is fueling illicit opioid addiction. According to the CDC, past misuse of prescription opioids is the strongest risk factor for a person starting and using heroin. Between 2000 and 2014, the number of overdose deaths from heroin nationwide quintupled. The death rate for heroin overdoses among Native Americans has also skyrocketed, rising 236 percent from 2010 to 2014.[10]

C. Pharmaceutical Defendants False, Deceptive And Unfair Marketing Of Opioids.

58. Each Pharmaceutical Defendant developed a well-funded marketing scheme based on deception to persuade doctors and patients that opioids can and should be used for treatment of chronic pain, resulting in opioid treatment for a far larger group, and for a longer time, for patients who are much more likely to become addicted. In connection with this scheme, each Pharmaceutical Defendants spent, and continued to spend, millions of dollars on promotional activities and materials that false deny or minimize the risks of opioids while overstating the benefit of using them for chronic pain.

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[9] US Medicine (2012). IHS Grapples with Pervasive Prescription Opioid Misuse in Tribal Areas. Addiction. Available at http://www.usmedicine.com/clinical- topics/addiction/ihs-grapples-with-pervasive-prescription-opioid-misuse-in-tribal-areas/

[10] Eugene Scott, *Native Americans, among the most harmed by the opioid epidemic, are often left out of the conversation*, Washington Post (Oct. 30, 2017), available at https://www.washingtonpost.com/news/the-fix/wp/2017/10/30/native- americans-among-the-most-harmed-by-the-opioid-epidemic-are-often-left-out-of- conversation/?utm_term=.3151c8bc8ecc (last accessed December 29, 2017).

59. The deceptive marketing schemes included, among others, (1) false or misleading direct, branded advertisements; (2) false or misleading direct-to-physician marketing, also known as "detailing;" (3) false or misleading materials speaker programs, webinars, and brochures; and (4) false or misleading unbranded advertisements or statements by purportedly neutral third parties that were really designed and distributed by the Pharmaceutical Defendants. In addition to using third parties to disguise the source of their misinformation campaign, the Pharmaceutical Defendants also retained the services of certain physicians, known as "key opinion leaders" or "KOLs" to convince both doctors and patients that opioids were safe for the treatment of chronic pain.

60. The Pharmaceutical Defendants have made false and misleading claims, contrary to the language on their drugs' labels regarding the risks of using their drugs that: (1) downplayed the seriousness of addiction; (2) created and promoted the concept of "pseudo addiction" when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools to prevent addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. The Pharmaceutical Defendants have also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support the Pharmaceutical Defendants' claims.

61. The Pharmaceutical Defendants have disseminated these common messages to reverse the popular and medical understanding of opioids and risks of opioid use. They disseminated these messages directly, through their sales representatives, in speaker groups led by physicians the Pharmaceutical Defendants recruited for their support of their marketing messages, through unbranded marketing and through industry-funded front groups.

62. These statements were not only unsupported by or contrary to the scientific evidence, they were also contrary to pronouncements by and guidance from the FDA and CDC based on that same evidence.

63. Pharmaceutical Defendant's efforts have been extremely successful. Opioids are now the most prescribed class of drugs. Globally, opioid sales generated $11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded $8 billion in revenue annually since 2009. In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."[11] This epidemic has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). When those patients can no longer afford or obtain opioids from licensed

[11] Letter from Vivek H. Murthy, U.S. Surgeon General (Aug. 2016), http://turnthetiderx.org/.

dispensaries, they often turn to the street to buy prescription opioids or even non-prescription opioids, like heroin.

64. Pharmaceutical Defendants intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

1. Each Pharmaceutical Defendant Used Multiple Avenues to Disseminate Their False and Deceptive Statements About Opioids

65. Pharmaceutical Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in and around the Ponca Nation. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the Ponca Tribe.

66. Pharmaceutical Defendants employed the same marketing plans and strategies and deployed the same messages in and around the Ponca Tribe, as they did nationwide. Across the opioid pharmaceutical industry, corporate headquarters funded and oversaw "core message" development on a national basis. This comprehensive approach ensures that the Pharmaceutical Defendants' messages are consistently delivered across marketing channels – including detailing visits, speaker events, and advertising – and in each sales territory. The Pharmaceutical Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

67. The Pharmaceutical Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local

medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks and sales training materials; and nationally coordinated advertising. The Pharmaceutical Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

i. Direct Marketing

68. The Pharmaceutical Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Pharmaceutical Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of opioids. For example, upon information and belief, the Pharmaceutical Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

69. Many of the Pharmaceutical Defendants' branded ads that deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker, chef, and teacher, misleadingly implying that the drug would provide long-term pain relief and functional improvement. Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively.

70. Each Pharmaceutical Defendant promoted the use of opioids for chronic pain through "detailers" – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs. The Pharmaceutical Defendants have not corrected this misinformation. Instead, each Defendant devoted massive resources to direct sales contacts with doctors. The Pharmaceutical Defendants spent in excess of $168 million in 2014 alone on detailing branded opioids to doctors, more than twice what they spent on detailing in 2000.

71. The Pharmaceutical Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Even without such studies, the Pharmaceutical Defendants purchase, manipulate, and analyze some of the most sophisticated data available in any industry, data available from IMS Health Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by individual doctor, which in turn allows them to target, tailor, and monitor the impact of their core messages. Thus, the Pharmaceutical Defendants know their detailing to doctors is effective.

72. The Pharmaceutical Defendants' detailers have been reprimanded for their deceptive promotions. In March 2010, for example, the FDA found that Actavis had been distributing promotional materials that "minimize[] the risks associated with Kadian and misleadingly suggest[] that Kadian is safer than has been demonstrated." Those materials

in particular "fail to reveal warnings regarding potentially fatal abuse of opioids, use by individuals other than the patient for whom the drug was prescribed."[12]

ii. Indirect Marketing

73. The Pharmaceutical Defendants indirectly marketed their opioids using unbranded advertising, paid speakers and "key opinion leaders" ("KOLs"), and industry-funded organizations posing as neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups").

74. The Pharmaceutical Defendants deceptively marketed opioids in the Ponca Tribe through unbranded advertising – e.g., advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, the Pharmaceutical Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as Defendants controlled the distribution of their "core messages" via their own detailers and speaker programs, they similarly controlled the distribution of these messages in scientific publications, treatment guidelines, Continuing Medical Education ("CME") programs, and medical conferences and seminars. To this end, the Pharmaceutical

[12] Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc'ns, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf.

Defendants used third-party public relations firms to help control those messages when they originated from third parties.

75. The Pharmaceutical Defendants marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. The Pharmaceutical Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, the Pharmaceutical Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long term opioid use for chronic pain.

76. Pharmaceutical Defendants also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Pharmaceutical Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Pharmaceutical Defendants' prior misrepresentations about the risks and benefits of opioids.

77. Borrowing a page from Big Tobacco's playbook, the Pharmaceutical Defendants worked through third parties they controlled by: (a) funding, assisting, encouraging and directing doctors who served as KOLS and (b) funding, assisting, directing and encouraging seemingly neutral and credible Front Groups. The Pharmaceutical Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, CME programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, the Pharmaceutical Defendants persuaded doctors and patients that what they have long known – that opioids are addictive drugs, unsafe in most circumstances for long- term use – was untrue, and that the compassionate treatment of pain required opioids.

78. In 2007, multiple States sued Purdue for engaging in unfair and deceptive practices in its marketing, promotion and sale of OxyContin. Certain states settled their claims in a series of Consent Judgments that prohibited Purdue from making misrepresentations in the promotion and marketing of OxyContin in the future. By using indirect marketing strategies, however, Purdue intentionally circumvented these restrictions. Such actions included contributing to the creation of misleading publications and prescribing guidelines, which lack a reliable scientific basis and promote prescribing practices that have worsened the opioid crisis.

79. Pro-opioid doctors are one of the most important avenues that the Pharmaceutical Defendants use to spread their false and deceptive statements about the risks and benefits of long- term opioid use. The Pharmaceutical Defendants know that doctors

rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with Purdue that the Purdue website "In the Face of Pain" failed to disclose that Purdue paid doctors who provided testimonials on the site and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials. Defendants utilized many KOLs, including many of the same ones.

80. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom the Pharmaceutical Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees and honoraria from Cephalon, Endo, Janssen and Purdue (among others) and was a paid consultant to Cephalon and Purdue. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS") / American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1996 and again in 2009. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by the Pharmaceutical Defendants.

81. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations, such as his claim that "the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low." He appeared on Good Morning America in 2010 to discuss the use of opioids long-

term to treat chronic pain. On this widely-watched program, broadcast across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that the person is not going to become addicted.[13]

82. Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist."[14] Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."[15]

83. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President of the American Academy of Pain Medicine ("AAPM") in 2013. He is a Senior Editor of Pain Medicine, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of

[13] Good Morning America (ABC television broadcast Aug. 30, 2010).
[14] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012, https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.
[15] *Id.*

numerous CMEs sponsored by Cephalon, Endo and Purdue. At the same time, Dr. Webster was receiving significant funding from the Pharmaceutical Defendants (including nearly $2 million from Cephalon).

84. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice's Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses.

85. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five-question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and, for this reason, references to screening appear in various industry- supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen and Purdue. Unaware of the flawed science and industry bias underlying this tool, certain states and public entities have incorporated the Opioid Risk Tool into their own guidelines, indicating, also, their reliance on the Pharmaceutical Defendants and those under their influence and control.

86. In 2011, Dr. Webster presented via webinar a program sponsored by Purdue entitled "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended use of risk screening tools, urine testing and patient agreements as a way to

prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors in the State of Oklahoma and doctors treating members of Plaintiff's community.[16]

87. Dr. Webster also was a leading proponent of the concept of "pseudo addiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to increase a patient's dose of opioids. As he and co-author Beth Dove wrote in their 2007 book Avoiding Opioid Abuse While Managing Pain—a book that is still available online—when faced with signs of abnormal behavior, increasing the dose "in most cases . . . should be the clinician's first response."[17] Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[18]

88. The Pharmaceutical Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of the

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[16] *See* Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the Need and the Risk*, http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Aug. 22, 2017).

[17] Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* (2007).

[18] John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012, http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn- 139609053.html.

Pharmaceutical Defendants, these "Front Groups" generated treatment guidelines, unbranded materials and programs that favored chronic opioid therapy. They also assisted the Pharmaceutical Defendants by responding to negative articles, advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence and conducting outreach to vulnerable patient populations targeted by the Pharmaceutical Defendants.

89. These Front Groups depended on the Pharmaceutical Defendants for funding and, in some cases, for survival. The Pharmaceutical Defendants also exercised control over programs and materials created by these groups by collaborating on, editing and approving their content and by funding their dissemination. In doing so, the Pharmaceutical Defendants made sure that the Front Groups would generate only the messages that the Pharmaceutical Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

90. Pharmaceutical Defendants Cephalon, Endo, Janssen and Purdue, in particular, utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), the Center for

Practical Bioethics ("CPB"), the U.S. Pain Foundation ("USPF") and the Pain & Policy Studies Group ("PPSG").[19]

91. The most prominent of the Pharmaceutical Defendants' Front Groups was the American Pain Foundation ("APF"), which, upon information and belief, received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012, primarily from Endo and Purdue. APF issued education guides for patients, reporters and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning veterans. APF also engaged in a significant multimedia campaign – through radio, television, and the internet – to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach citizens of the Ponca Tribe.

92. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of a total income of about $2.85 million in 2009; its budget for 2010 projected receipts of roughly $2.9 million from drug companies, out of total income of about $3.5 million. By 2011, upon information and belief,

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[19] *See generally, e.g.*, Letter from Sen. Ron Wyden, U.S. Senate Comm. on Fin., to Sec. Thomas E. Price, U.S. Dep't of Health and Human Servs., (May 5, 2015), https://www.finance.senate.gov/imo/media/doc/050517%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group.pdf.

APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo and others to avoid using its line of credit.

93. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing and thus the profitability of its sponsors. Upon information and belief, it was often called upon to provide "patient representatives" for the Pharmaceutical Defendants' promotional activities, including for Purdue's Partners Against Pain and Janssen's Let's Talk Pain. APF functioned largely as an advocate for the interests of the Pharmaceutical Defendants, not patients. Indeed, upon information and belief, as early as 2001, Purdue told APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

94. Plaintiff is informed, and believes, that on several occasions representatives of the Pharmaceutical Defendants, often at informal meetings at conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

95. The U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and the Pharmaceutical Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board

voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."[20]

96. Another front group for the Pharmaceutical Defendants was the American Academy of Pain Medicine ("AAPM"). With the assistance, prompting, involvement, and funding of the Pharmaceutical Defendants, the AAPM issued purported treatment guidelines and sponsored and hosted medical education programs essential to the Pharmaceutical Defendants' deceptive marketing of chronic opioid therapy.

97. AAPM received substantial funding from opioid manufacturers. For example, AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Pharmaceutical Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event.

[20] Charles Ornstein & Tracy Weber, Senate Panel Investigates Drug Companies' Ties to Pain Groups, Wash. Post, May 8, 2012, https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies- ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html.

98. Upon information and belief, AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation.

99. The Pharmaceutical Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

100. In 1996, AAPM and APS jointly issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," which endorsed opioids to treat chronic pain and claimed that the risk of a patients' addiction to opioids was low. Dr. Haddox, who co-authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and, upon information and belief, was taken down from AAPM's website only after a doctor complained.[21]

[21] *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society*, 13 Clinical J. Pain 6 (1997).

101. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain.[22] Doctors, especially the general practitioners and family doctors targeted by the Pharmaceutical Defendants, have relied upon treatment guidelines. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

102. At least 14 of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Pharmaceutical Defendants Janssen, Cephalon, Endo, and Purdue. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories.[23] One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Pharmaceutical Defendants, made to the sponsoring organizations and committee

[22] Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain*, 10 J. Pain 113 (2009).
[23] *Id.*

members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited hundreds of times in academic literature, were disseminated in the Ponca Tribe during the relevant time period, are still available online, and were reprinted in the Journal of Pain. The Pharmaceutical Defendants widely referenced and promoted the 2009 Guidelines without disclosing the lack of evidence to support them or the Pharmaceutical Defendants financial support to members of the panel.

103. The Pharmaceutical Defendants worked together through Front Groups to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Defendants combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Cephalon, Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from the Pharmaceutical Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which the Pharmaceutical Defendants determined would reduce prescribing.

D. Pharmaceutical Defendants' Marketing Scheme Misrepresented The Risks And Benefits of Opioids.

1. The Pharmaceutical Defendants embarked upon a campaign of false, deceptive, and unfair assurances grossly understating and misstating the dangerous addiction risks of the opioid drugs.

104. To falsely assure physicians and patients that opioids are safe, the Pharmaceutical Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low risk because most patients would not become addicted, and because those at greatest risk for addiction could be identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. The Pharmaceutical Defendants have not only failed to correct these misrepresentations, they continue to make them today.

105. Opioid manufacturers, including Pharmaceutical Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have entered into settlement agreements with public entities that prohibit them from making many of the misrepresentations identified in this Complaint. Yet even afterward, each Pharmaceutical Defendant continued to misrepresent the risks and benefits of long-term opioid use in the Ponca Tribe and each continues to fail to correct its past misrepresentations.

106. Some illustrative examples of the Pharmaceutical Defendants' false, deceptive, and unfair claims about the purportedly low risk of addiction include:

a. Actavis's predecessor caused a patient education brochure,

Managing Chronic Back Pain, to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely claimed that it is "less likely if you have never had an addiction problem." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond.

b. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.

c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Upon information and belief, another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." Endo also distributed an "Informed Consent" document on PainAction.com that misleadingly suggested that only people who "have problems with substance abuse and addiction" are likely to become addicted to opioid medications.

d. Upon information and belief, Endo distributed a pamphlet with the Endo logo entitled Living with Someone with Chronic Pain, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem."

e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

f. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."

g. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which claims that less

than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "[m]isconceptions about opioid addiction."[24]

h. Consistent with the Pharmaceutical Defendants' published marketing materials, upon information and belief, detailers for Purdue, Endo, Janssen, and Cephalon in Oklahoma and Plaintiff's community minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

i. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Pharmaceutical Defendants' Front Groups APF and NFP argued in an amicus brief to the United States Fourth Circuit Court of Appeals that "patients rarely become addicted to prescribed opioids," citing research by their KOL, Dr. Portenoy.[25]

107. These claims are contrary to longstanding scientific evidence. A 2016 opioid-prescription guideline issued by the CDC (the "2016 CDC Guideline") explains that there is "[e]xtensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction], [and] overdose . . .)."[26] The 2016 CDC Guideline further explains that "[o]pioid pain medication use presents serious risks, including

[24] Am. Pain Found., *A Policymaker's Guide to Understanding Pain and Its Management* 6 (2011) [hereinafter APF, *Policymaker's Guide*], http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

[25] Brief of the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No. 05-4474 (4th Cir. Sept. 8, 2005) [hereinafter Brief of APF] at 9.

[26] Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity & Mortality Wkly. Rep., Mar. 18, 2016, at 15 [hereinafter 2016 CDC Guideline], https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

overdose and opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[27]

108. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for extended-release and long-acting ("ER/LA") opioids in 2013 and for immediate release ("IR") opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed.[28]

109. The State of New York, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary

[27] *Id.* at 2, 25.

[28] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Andrew Koldny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf.; Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan and Becker, LLP (Mar. 22, 2016), https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf.

care outpatient centers meeting the clinical criteria for an opioid use disorder."[29] Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the State of New York found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. Endo remains free, however, to make those statements within the Ponca Tribe.

110. In addition to mischaracterizing the highly addictive nature of the drugs they were pushing, Pharmaceutical Defendants also fostered a fundamental misunderstanding of the signs of addiction. Specifically, the Pharmaceutical Defendants misrepresented, to both doctors and patients, that warning signs and/or symptoms of addiction were, instead, signs of undertreated pain (i.e. "pseudoaddiction") – and instructed doctors to increase the opioid prescription dose for patients who were already in danger.

111. In the 2016 CDC Guideline, the CDC rejects the validity of the pseudoaddiction fallacy invented by a Purdue employee as a reason to push more opioid drugs onto already addicted patients.

112. In addition to misstating the addiction risk and inventing the pseudoaddiction falsehood, a third category of false, deceptive, and unfair practice is the

[29] Assurance of Discontinuance, *In re Endo Health Solutions Inc. and Endo Pharm. Inc.* (Assurance No. 15-228), at 16, https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

Pharmaceutical Defendants' false instructions that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because the Pharmaceutical Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. The Pharmaceutical Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting on opioid therapy for chronic pain. Illustrative examples include:

a. Endo paid for a 2007 supplement in the Journal of Family Practice written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled Pain Management Dilemmas in Primary Care: Use of Opioids, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

b. Purdue, upon information and belief, sponsored a 2011 webinar, Managing Patient's Opioid Use: Balancing the Need and Risk, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

c. As recently as 2015, upon information and belief, Purdue has represented in scientific conferences that "bad apple" patients – and not opioids – are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

d. On information and belief, detailers for the Pharmaceutical Defendants have touted and continue to tout to doctors in Oklahoma the reliability and effectiveness of screening or monitoring patients as a tool for managing opioid abuse and addiction.

113. Once again, the 2016 CDC Guideline confirms that these statements were false, misleading, and unsupported at the time they were made by the Pharmaceutical Defendants. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse – "for improving outcomes related to overdose, addiction, abuse, or misuse." As a result, the Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

114. To underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, the Pharmaceutical Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and failed to disclose the increased difficulty of stopping opioids after long-term use.

115. For example, on information and belief, a 2011 non-credit educational program sponsored by Endo, entitled Persistent Pain in the Older Adult, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days.

116. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which claimed that "[s]ymptoms of physical dependence can often be

ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur."[30]

117. The Pharmaceutical Defendants deceptively minimized the significant symptoms of opioid withdrawal – which, as explained in the 2016 CDC Guideline, include drug craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, tremor, and tachycardia (rapid heartbeat) – and grossly understated the difficulty of tapering, particularly after long-term opioid use.

118. Contrary to the Pharmaceutical Defendants' representations, the 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms," because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days." (Emphasis added). The Guideline further states that "more than a few days of exposure to opioids significantly increases hazards" and "each day of unnecessary opioid use increases likelihood of physical dependence without adding benefit."

119. The Pharmaceutical Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to the Pharmaceutical Defendants' efforts to market opioids for long-term use to treat chronic pain

[30] Available at, http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf (last accessed December 19, 2017).

because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. Some illustrative examples of these deceptive claims are described below:

a. On information and belief, Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction."

b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. This guide is still available online.[31]

c. Endo sponsored a website, "PainKnowledge," which, upon information and belief, claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004 endo Pharmaceuticals PM-0120). In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . .You won't 'run out' of pain relief."[32]

e. Janssen, on information and belief, sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but

[31] Available at, https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf (last accessed December 19, 2017).

[32] Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K Portenoy, M.D., ed., 2004).

omitted any discussion of risks of increased opioid dosages.

f. On information and belief, Purdue's *In the Face of Pain* website promoted the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online.

h. In 2007, Purdue sponsored a CME entitled "Overview of Management Options" that was available for CME credit and available until at least 2012. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

i. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Front Group APF and others argued to the United States Fourth Circuit Court of Appeals that "there is no 'ceiling dose'" for opioids.

j. On information and belief, Purdue's detailers have told doctors in Oklahoma that they should increase the dose of OxyContin, rather than the frequency of use, to address early failure.

120. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at

higher opioid dosages." The CDC also states that there are "increased risks for opioid use disorder, respiratory depression, and death at higher dosages."

121. The Pharmaceutical Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can prevent and curb addiction and abuse.

122. These abuse deterrent formulations (AD opioids) purportedly are harder to crush, chew, or grind; become gelatinous when combined with a liquid, making them harder to inject; or contain a counteragent such as naloxone that is activated if the tablets are tampered. Despite this, AD opioids can be defeated – often quickly and easily – by those determined to do so. The 2016 CDC Guideline state that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies—even when they work—do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes. Moreover, they do not reduce the rate of misuse and abuse by patients who become addicted after using opioids long- term as prescribed or who escalate their use by taking more pills or higher doses. Tom Frieden, the Director of the CDC, has further reported that his staff could not find "any evidence showing the updated opioids [ADFs] actually reduce rates of addiction, overdoses, or death."[33]

[33] Matthew Perrone et al., *Drugmakers push profitable, but unproven, opioid solution*, Center for Public Integrity (Dec. 15, 2016), available at https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution (last accessed December 20, 2017).

123. Despite this lack of evidence, the Pharmaceutical Defendants have made and continue to make misleading claims about the ability of their so-called abuse-deterrent opioid formulations to prevent or reduce abuse and addiction and the safety of these formulations.

124. For example, Endo has marketed Opana ER[34] as tamper- or crush- resistant and less prone to misuse and abuse since even though: (1) on information and belief, the FDA warned in a 2013 letter that there was no evidence that Opana ER would provide a reduction in oral, intranasal or intravenous abuse; and (2) Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. Nonetheless, Endo's advertisements for Opana ER falsely claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. And on information and belief, detailers for Endo have informed doctors that Opana ER is harder to abuse. Likewise, Purdue has engaged and continues to engage in deceptive marketing of its AD opioids – i.e., reformulated Oxycontin and Hysingla. Before April 2013, Purdue did not market its opioids based on their abuse deterrent properties. However, beginning in 2013 and continuing today, detailers from Purdue regularly use the so-called abuse deterrent properties of

[34] Because Opana ER could be "readily prepared for injection" and was linked to outbreaks of HIV and a serious blood disease, in May 2017, an FDA advisory committee recommended that Opana ER be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017 and requested that Endo withdraw Opana ER from the market. Press Release, "FDA requests removal of Opana ER for risks related to abuse," June 8, 2017, available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm (last accessed December 20, 2017).

Purdue's opioid products as a primary selling point to differentiate those products from their competitors. Specifically, on information and belief, these detailers: (1) falsely claim that Purdue's AD opioids prevent tampering and cannot be crushed or snorted; (2) falsely claim that Purdue's AD opioids prevent or reduce opioid misuse, abuse, and diversion, are less likely to yield a euphoric high, and are disfavored by opioid abusers; (3) falsely claim Purdue's AD opioids are "safer" than other opioids; and (4) fail to disclose that Purdue's AD opioids do not impact oral abuse or misuse and that its abuse deterrent properties can be defeated.

125. These statements and omissions by Purdue are false and misleading. Purdue knew and should have known that reformulated OxyContin is not better at tamper resistance than the original OxyContin and is still regularly tampered with and abused. A 2015 study also shows that many opioid addicts are abusing Purdue's AD opioids through oral intake or by defeating the abuse deterrent mechanism. Indeed, one-third of the patients in the study defeated the abuse deterrent mechanism and were able to continue inhaling or injecting the drug. And to the extent that the abuse of Purdue's AD opioids was reduced, those addicts simply shifted to other drugs such as heroin.[35] Despite this, J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's AD opioids are being abused in large numbers.[36]

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[35] Cicero, Theodore J., and Matthew S. Ellis, "Abuse-deterrent formulations and the prescription opioid abuse epidemic in the United States: lessons learned from Oxycontin" (2015) 72.5 *JAMA Psychiatry* 424-430.

[36] See Harrison Jacobs, *There is a big problem with the government's plan to stop the drug-overdose epidemic*, Business Insider, Mar. 14, 2016, available at

126. The development, marketing, and sale of AD opioids is a continuation of the Pharmaceutical Defendants' strategy to use misinformation to drive profit. The Pharmaceutical Defendants' claims that AD opioids are safe falsely assuage doctors' concerns about the toll caused by the explosion in opioid abuse, causing doctors to prescribe more AD opioids, which are far more expensive than other opioid products even though they provide little or no additional benefit.

2. The Pharmaceutical Defendants embarked upon a campaign of false, deceptive, and unfair assurances grossly overstating the benefits of the opioid drugs.

127. To convince doctors and patients that opioids should be used to treat chronic pain, the Pharmaceutical Defendants also had to persuade them that there was a significant upside to long- term opioid use. But as the CDC Guideline makes clear, "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use.[37] The FDA, too, has recognized the lack of evidence to support long-term opioid use. Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence.

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http://www.businessinsider.com/robert-califf-abuse-deterrent-drugs-have-a-big-flaw-2016-3 (last accessed December 20, 2017).

[37] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Robert Barto, Vice President, Reg. Affairs, Endo Pharm. Inc. (May 10, 2013), at 5.

128. Some illustrative examples of the Pharmaceutical Defendants' false claims are:

a. Upon information and belief, Actavis distributed an advertisement claiming that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.

c. Janssen sponsored and edited a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.

d. Janssen promoted Ultracet for everyday chronic pain and distributed posters, for display in doctors' offices, of presumed patients in active professions; the caption read, "Pain doesn't fit into their schedules."

e. Upon information and belief, Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves the patients' function.

f. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function.

g. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which counseled patients that opioids "give [pain patients] a quality of life we

deserve."[38]

h. Endo's NIPC website "PainKnowledge" claimed in 2009, upon information and belief, that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

i. Endo was the sole sponsor, through NIPC, of a series of CMEs entitled "Persistent Pain in the Older Patient." Upon information and belief, a CME disseminated via webcast claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."

j. Janssen sponsored and funded a multimedia patient education campaign called "Let's Talk Pain." One feature of the campaign was to complain that patients were under-treated. In 2009, upon information and belief, a Janssen-sponsored website, part of the "Let's Talk Pain" campaign, featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function."

k. Purdue sponsored the development and distribution of APF's A Policymaker's Guide to Understanding Pain & Its Management, which claimed that "[m]ultiple clinical studies" have shown that opioids are effective in improving "[d]aily function," "[p]sychological health," and "[o]verall health-related quality of life for chronic pain." The Policymaker's Guide was originally published in 2011.

3. Purdue's, Cephalon's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

[38] Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter APF, *Treatment Options*], https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.

129. As the FDA and other agencies have made clear for years, these claims have no support in scientific literature.

130. In 2010, the FDA warned Actavis, in response to its advertising of Kadian described above, that "we are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[39] And in 2008, upon information and belief, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

131. The Pharmaceutical Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing medications like NSAIDs (nonsteroidal anti-inflammatory drugs), so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by the Pharmaceutical Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016

[39] Letter from Thomas Abrams to Doug Boothe, *supra* note 14.

CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain. The Pharmaceutical Defendants have overstated the number of deaths from NSAIDS and have prominently featured the risks of NSAIDS, while minimizing or failing to mention the serious risks of opioids.

132. For example, Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all times relevant to this action. Upon information and belief, Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial proportion" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

133. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-

based IR opioids. Neither is approved for, or has been shown to be safe or effective for, chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm.

134. Despite this, on information and belief, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe.[40] As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain.

135. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses. For example:

a. Cephalon paid to have a CME it sponsored, Opioid-Based Management of Persistent and Breakthrough Pain, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "[c]linically, broad classification of pain syndromes as either cancer- or non-cancer- related has limited utility" and recommended Actiq and Fentora for patients with chronic pain.

b. Upon information and belief, Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

[40] *See* Press Release, U.S. Dep't of Justice, *Biopharmaceutical Company, Cephalon, to Pay $425 million & Enter Plea To Resolve Allegations of Off-Label Marketing* (Sept. 29, 2008), https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html (last accessed December 21, 2017).

c. In December 2011, Cephalon widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News, and Pain Medicine News – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

136. The Pharmaceutical Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The Pharmaceutical Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of the Pharmaceutical Defendants' misrepresentations.

137. On information and belief, the Pharmaceutical Defendants coordinated their messaging through national and regional sales and speaker trainings and coordinated advertisements and marketing materials.

138. Moreover, at all times relevant to this Complaint, the Pharmaceutical Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Pharmaceutical Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. The Pharmaceutical Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the Pharmaceutical Defendants' false and misleading statements about the risks and benefits of long-term opioid use for chronic pain.

139. Finally, the Pharmaceutical Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. The Pharmaceutical Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for the Pharmaceutical Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could the Ponca Tribe have detected it.

140. The Pharmaceutical Defendants' efforts to artificially increase the number of opioid prescriptions directly and predictably caused a corresponding increase in opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has

quadrupled since 1999 and has increased in parallel with [opioid] overdoses."[41] Many abusers start with legitimate prescriptions. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "[t]o reverse the epidemic of opioid drug overdose deaths and prevent opioid- related morbidity."[42] Accordingly, the Pharmaceutical Defendants' false and misleading statements directly caused the current opioid epidemic.

E. Distributor Defendants' Unlawful Distribution of Opioids

141. The Distributor Defendants owe a duty under federal law (21 U.S.C. § 823, 21 CFR 1301.74) to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating from Plaintiff's Community as well as those orders which the Distributor Defendants knew or should have known were likely to be diverted into Plaintiff's Community.

142. The foreseeable harm from a breach of these duties is the diversion of prescription opioids for nonmedical purposes.

143. Each Distributor Defendant repeatedly and purposefully breached its duties under tribal, state, and federal law. Such breaches are a direct and proximate causes of the widespread diversion of prescription opioids for nonmedical purposes into Plaintiff's community.

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[41] Rose A Rudd, et al., *Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014*, Morbidity and Mortality Wkly Rep. (Jan. 1, 2016), available at https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm (last accessed December 20, 2017).

[42] *Id.*

144. The unlawful diversion of prescription opioids is a direct and proximate cause of the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the Ponca Tribe. This diversion and the epidemic are direct causes of harms for which Plaintiff seeks to recover here.

145. The opioid epidemic in the Ponca Tribe remains an immediate ***hazard to public health and safety***.

146. The Distributor Defendants' intentionally continued their conduct, as alleged herein, with knowledge that such conduct was creating the opioid nuisance and causing the harms and damages alleged herein.

1. The Distributor Defendants Negligently Failed To Control The Flow Of Opioids Into The Ponca Tribe Through Illicit Channels

147. The DEA has provided guidance to distributors to combat opioid diversion. On information and belief, since 2006 the DEA has conducted one-on-one briefings with distributors regarding downstream customer sales, due diligence, and regulatory responsibilities. The DEA also provides distributors with data on controlled substance distribution patterns and trends, including data on the volume and frequency of orders and the percentage of controlled versus non-controlled purchases. On information and belief, the DEA has also hosted conferences for opioid distributors and has participated in numerous meetings and events with trade associations.

148. On September 27, 2006, and December 27, 2007, the DEA Office of Diversion Control sent letters to all registered distributors providing guidance on suspicious order monitoring and the responsibilities and obligations of registrants to prevent diversion.

149. As part of the legal obligation to maintain effective controls against diversion, the distributor is required to exercise due care in confirming the legitimacy of each and every order prior to filling. Circumstances that could be indicative of diversion include ordering excessive quantities of a limited variety of controlled substances while ordering few if any other drugs; ordering a disproportionate amount of controlled substances versus non-controlled prescription drugs; ordering excessive quantities of a limited variety of controlled substances in combination with lifestyle drugs; and ordering the same controlled substance from multiple distributors.

150. Suspicious orders must be reported when discovered. Registrants must perform an independent analysis of a suspicious order prior to the sale to determine if the controlled substances would likely be diverted, and filing a suspicious order and then completing the sale does not absolve the registrant from legal responsibility.

151. On information and belief, the Distributor Defendants' own industry group, the Healthcare Distribution Management Association, published Industry Compliance Guidelines titled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances" emphasizing the critical role of each member of the supply chain in distributing controlled substances. These industry guidelines stated: "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."

152. Opioid distributors have admitted to the magnitude of the problem and, at least superficially, their legal responsibilities to prevent diversion. They have made

statements assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.

153. These assurances, on their face, of identifying and eliminating criminal activity and curbing the opioid epidemic create a duty for the Distributor Defendants to take reasonable measures to do just that.

154. Despite their duties to prevent diversion, the Distributor Defendants have knowingly or negligently allowed diversion.[43] The DEA has repeatedly taken action to attempt to force compliance, including 178 registrant actions between 2008 and 2012, 76 orders to show cause issued by the Office of Administrative Law Judges, and 41 actions involving immediate suspension orders.[44] The Distributor Defendants' wrongful conduct and inaction have resulted in numerous civil fines and other penalties, including:

a. In a 2017 Administrative Memorandum of Agreement between McKesson and the DEA, McKesson admitted that it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."

[43] Scott Higham and Lenny Bernstein, *The Drug Industry's Triumph Over the DEA*, Wash. Post, Oct. 15, 2017, available at https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/?utm_term=.75e86f3574d3 (last accessed December 21, 2017); Lenny Bernstein, David S. Fallis, and Scott Higham, *How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job,'* Wash. Post, Oct. 22, 2016, available at https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?tid=graphics-story&utm_term=.4f439ef106a8 (last accessed December 21, 2017).

[44] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), available at https://oig.justice.gov/reports/2014/e1403.pdf (las accessed January 8, 2018).

McKesson was fined $150,000,000.[45]

b. McKesson has a history of repeatedly failing to perform its duties. In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the Country, resulting in millions of doses of controlled substances being diverted. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer.

c. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Auburn, Washington, for failure to maintain effective controls against diversion.

d. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion.

e. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Swedesboro, New Jersey, for failure to maintain effective controls against diversion.

f. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Stafford, Texas, for failure to maintain effective controls against diversion.

g. In 2008, Cardinal paid a $34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in

[45] Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17, 2017), available at https://www.justice.gov/opa/press-release/file/928476/download (last accessed December 21, 2017).

the United States.[46]

h. On February 2, 2012, the DEA issued another Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion.

i. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states.

j. In December 2016, the Department of Justice announced a multi-million dollar settlement with Cardinal for violations of the Controlled Substances Act.[47]

k. On information and belief, in connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to a particular pharmacy in Wisconsin that was suspected of opioid diversion. Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacy. Cardinal did just the opposite, pumping up opioid shipments to the pharmacy to almost 2,000,000 doses of oxycodone in one year, while other comparable pharmacies were receiving approximately 69,000 doses/year.

l. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies.

m. In 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically

[46] Lenny Bernstein and Scott Higham, *Cardinal Health fined $44 million for opioid reporting violations*, Wash. Post, Jan. 11, 2017, available at https://www.washingtonpost.com/national/health-science/cardinal-health-fined-44-million-for-opioid-reporting-violations/2017/01/11/4f217c44-d82c-11e6-9a36-1d296534b31e_story.html?utm_term=.0c8e17245e66 (last accessed December 21, 2017).

[47] Press Release, United States Dep't of Justice, *Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act*, Dec. 23, 2016, available at https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million- settlement-alleged-violations-controlled-substances-act (last accessed December 21, 2017).

necessary channels.

155. Although law enforcement authorities have penalized distributors, these penalties have not changed their conduct. They pay fines as a cost of doing business in an industry that generates billions of dollars in revenue and profit.

156. The Distributor Defendants' failure to prevent the foreseeable injuries from opioid diversion created an enormous black market for prescription opioids, which market extended to the Ponca Tribe and its members. Each Distributor Defendant knew or should have known that the opioids reaching the Ponca Tribe was not being consumed for medical purposes and that the amount of opioids flowing to Oklahoma was far in excess of what could be consumed for medically necessary purposes.

157. The Distributor Defendants negligently or intentionally failed to adequately control their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled substances would have anticipated the danger of opioid diversion and protected against it by, for example, taking greater care in hiring, training, and supervising employees; providing greater oversight, security, and control of supply channels; looking more closely at the pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in amounts greater than the populations in those areas would warrant; investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers in and around Plaintiff's community; providing information to pharmacies and retailers about opioid diversion; and in general, simply following applicable statutes, regulations, professional standards, and guidance from government agencies and using a little bit of common sense.

158. On information and belief, the Distributor Defendants made little to no effort to visit the pharmacies servicing the areas around Plaintiff's community to perform due diligence inspections to ensure that the controlled substances the Distributor Defendants had furnished were not being diverted to illegal uses.

159. On information and belief, the compensation the Distributor Defendants provided to certain of their employees was affected, in part, by the volume of their sales of opioids to pharmacies and other facilities servicing the areas around Plaintiff's community, thus improperly creating incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid abuse.

160. It was reasonably foreseeable to the Distributor Defendants that their conduct in flooding the market in and around Plaintiff's community with highly addictive opioids would allow opioids to fall into the hands of children, addicts, criminals, and other unintended users.

161. It is reasonably foreseeable to the Distributor Defendants that, when unintended users gain access to opioids, tragic preventable injuries will result, including addiction, overdoses, and death. It is also reasonably foreseeable that many of these injuries will be suffered by the Ponca Tribe members, and that the costs of these injuries will be borne by the Ponca Tribe.

162. The Distributor Defendants knew or should have known that the opioids being diverted from their supply chains would contribute to the opioid epidemic faced by the Ponca Tribe, and would create access to opioids by unauthorized users, which, in turn,

perpetuates the cycle of addiction, demand, illegal transactions, economic ruin, and human tragedy.

163. The Distributor Defendants were aware of widespread prescription opioid abuse in and around Plaintiff's community, but, on information and belief, they nevertheless persisted in a pattern of distributing commonly abused and diverted opioids in geographic areas-and in such quantities, and with such frequency that they knew or should have known these commonly abused controlled substances were not being prescribed and consumed for legitimate medical purposes.

164. The use of opioids by Ponca Tribe members who were addicted or who did not have a medically necessary purpose could not occur without the knowing cooperation and assistance of the Distributor Defendants. If the Distributor Defendants adhered to effective controls to guard against diversion, the Tribe and its members would have avoided significant injury.

165. The Distributor Defendants made substantial profits over the years based on the diversion of opioids into Oklahoma. The Distributor Defendants knew that the Ponca Tribe would be unjustly forced to bear the costs of these injuries and damages.

166. The Distributor Defendants' intentional distribution of excessive amounts of prescription opioids within Oklahoma showed an intentional or reckless disregard for the safety of the Ponca Tribe and its members. Their conduct poses a continuing threat to the health, safety, and welfare of the Tribe.

167. The Distributor Defendants' violations constitute prima facie evidence of negligence.

2. The Pharmaceutical Defendants Negligently Failed to Control The Flow Of Opioids Within the Ponca Tribe Through Illicit Channels

168. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescriptions opioids that were incumbent upon the Distributor Defendants were also legally required of the Pharmaceutical Defendants under federal law.

169. Like the Distributor Defendants, the Pharmaceutical Defendants are required to design and operate a system to detect suspicious orders, and to report such orders to law enforcement. (See 21 C.F.R. § 1301.74(b); 21 U.S.C. § 823). The Pharmaceutical Defendants have not done so.

170. On information and belief, for over a decade the Pharmaceutical Defendants have been able to track the distribution and prescribing of their opioids down to the retail and prescriber level. Thus, the Pharmaceutical Defendants had actual knowledge of the prescribing practices of doctors, including red flags indicating diversion. The Pharmaceutical Defendants did not report those red flags, nor did they cease marketing to those doctors. Like the Distributor Defendants, the Pharmaceutical Defendants breached their duties under federal and state law.

171. The Pharmaceutical Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. The Pharmaceutical Defendants engaged in the practice of paying "chargebacks" to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor

requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, the Pharmaceutical Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Pharmaceutical Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

172. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law (21 C.F.R. § 1301.74(b); 21 U.S.C. § 823(a)(1)), fining Mallinckrodt $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[48] Among the allegations resolved by the settlement, the government alleged "Mallinckrodt failed to design and implement an effective system to detect and report suspicious orders for controlled substances – orders that are unusual in their frequency, size, or other patterns. . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[49] Mallinckrodt agreed that its "system to monitor and detect suspicious orders did not meet the standards outlined in letters from the

[48] *See* Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million- settlement-failure-report-suspicious- orders.

[49] *Id.*

DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007."[50]

173. Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Through its extensive network of sales representatives, Purdue had and continues to have knowledge of the prescribing practices of thousands of doctors and could identify doctors who displayed red flags for diversion such as those whose waiting rooms were overcrowded, whose parking lots had numerous out-of-state vehicles, and whose patients seemed young and healthy or homeless. Using this information, Purdue has maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs.[51] Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In doing so, Purdue protected its own profits at the expense of public health and safety.

174. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo,

[50] 2017 Mallinckrodt MOA at p. 2-3.

[51] Scott Glover and Lisa Girion, *OxyContin maker closely guards its list of suspect doctors*, L.A. Times, August 11, 2013, available at http://articles.latimes.com/2013/aug/11/local/la-me-rx-purdue-20130811 (last accessed December 20, 2017).

the NY AG found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list. The NY AG also found that, in certain cases where Endo's sales representatives detailed prescribers who were convicted of illegal prescribing of opioids, those representatives could have recognized potential signs of diversion and reported those prescribers but failed to do so.

175. On information and belief, the other Pharmaceutical Defendants have engaged in similar conduct in violation of their responsibilities to prevent diversion.

176. The Pharmaceutical Defendants' actions and omission in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids into Oklahoma.

F. Defendants' Unlawful Conduct And Breaches Of Legal Duties Caused The Harm Alleged Herein And Substantial Damages

177. As the Pharmaceutical Defendants' efforts to expand the market for opioids increased so have the rates of prescription and sale of their products — and the rates of opioid-related substance abuse, hospitalization, and death among the people of the Ponca Tribe. The Distributor Defendants have continued to unlawfully ship these massive quantities of opioids into communities like the Plaintiff's community, fueling the epidemic.

178. As shown above, the opioid epidemic has escalated in Plaintiff's community with devastating effects. Substantial opiate-related substance abuse, hospitalization and death that mirrors Defendants' increased distribution of opiates.

179. Because of the well-established relationship between the use of prescription opiates and the use of non-prescription opioids, like heroin, the massive distribution of opioids to Plaintiff's community and areas from which such opioids are being diverted into Plaintiff's community, has caused the Defendant-caused opioid epidemic to include heroin addiction, abuse, and death.

180. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to public health and safety to the Ponca Tribe.

181. Heroin abuse, addiction, morbidity, and mortality are hazards to public health and safety to the Ponca Tribe.

182. Defendants repeatedly and purposefully breached their duties under tribal, state and federal law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes into the Ponca Tribe.

183. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the Ponca Tribe. This diversion and the epidemic are direct causes of foreseeable harms incurred by the Plaintiff.

184. Defendants' intentional and/or unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Plaintiff seeks relief, as

alleged herein. Plaintiff also seeks the means to abate the nuisance of the opioid epidemic created by Defendants' wrongful and/or unlawful conduct.

185. Plaintiff seeks economic damages from the Defendants as reimbursement for the costs association with past efforts to eliminate the hazards to public health and safety.

186. Plaintiff seeks economic damages from the Defendants to pay for the cost to permanently eliminate the hazards to public health and safety and abate the public nuisance.

187. Having profited enormously through the aggressive sale, misleading promotion, and irresponsible distribution of opiates, Defendants should be required to take responsibility for the financial burdens their conduct has inflicted upon the Plaintiff and Plaintiff's community.

G. Statutes Of Limitations Are Tolled And Defendants Are Estopped From Asserted Statutes Of Limitations As Defenses

188. Plaintiff contends it continues to suffer harm from the continual unlawful actions by Defendants.

189. The continued tortious and unlawful conduct by the Defendants are continuing violations of federal, state and tribal law causing a distinct injury instead of continual ill effects from an original violation. The effects of Defendants' continuing violations are cumulative. The damages have not occurred all at once but have continued to occur after each violation and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The

wrongdoing and unlawful activity by Defendants has not ceased. The public nuisance remains unabated.

190. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assure the public that they were undertaking efforts to comply with their obligations under the controlled substances laws, all with the goal of continuing to generate profits.

191. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain, and assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[52]

192. Similarly, McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[53]

[52] Lenny Bernstein et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job,"* Wash. Post, Oct. 22, 2016, available at https://www.washingtonpost.com/investigations/how-drugs-intended-for- patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their- job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html (last accessed December 21, 2017)

[53] Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post, Dec. 22, 2016, available at https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html (last accessed December 21, 2017).

193. Defendants purposely concealed their wrongful conduct, including by assuring the public and governmental authorities that they were complying with their obligations and were acting to prevent diversion and drug abuse. Defendants also misrepresented the impact of their behavior by providing the public with false information about opioids and have continued to use Front Groups and third parties to minimize the risks of Defendants' conduct.

194. Defendants have also concealed and prevented discovery of information, including data from the ARCOS database, that will confirm their identities and the extent of their wrongful and illegal activities.

195. Defendants also lobbied Congress and actively attempted to halt DEA investigations and enforcement actions and to subvert the ability of agencies to regulate their conduct.[54] As a result, there was a sharp drop in enforcement actions and the standard for the DEA to revoke a distributor's license was raised.

196. In addition, the Defendants fraudulently attempted to convince the public that they were complying with their legal obligations and working to curb the opioid epidemic.

197. Because the Defendants concealed the facts surrounding the opioid epidemic, the Ponca Tribe did not know of the existence or scope of the Defendants' misconduct, and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

[54] *See* Higham and Bernstein, *supra* note 45.

198. Defendants intended that their false statements and omissions be relied upon, including by the Ponca Tribe, its community, and its members.

199. Defendants knew of their wrongful acts and had material information pertinent to their discovery, but concealed that information from the public, including the Ponca Tribe, its community and its members. Only Defendants knew of their widespread misinformation campaign and of their repeated, intentional failures to prevent opioid diversion.

200. Defendants cannot claim prejudice due to a late filing because this suit was filed upon discovering the facts essential to the claim. Indeed, the existence, extent, and damage of the opioid crisis have only recently come to light.

201. Defendants had actual knowledge that their conduct was deceptive, and they intended it to be deceptive.

202. The Ponca Tribe was unable to obtain vital information regarding these claims absent any fault or lack of diligence on the Tribe's part.

203. Defendants intended that their actions and omissions would be relied upon, including by Plaintiff and Plaintiff's community. Plaintiff and Plaintiff's community did not know and did not have the means to know the truth, due to Defendants' actions and omissions.

204. The Plaintiff and Plaintiff's community reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

V. CAUSES OF ACTION

COUNT I: RACKETEER-INFLUENCED AND CORRUPT ORGANIZATIONS ACT, 18 U.S.C. § 1961 et seq.

205. The Ponca Tribe incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

206. Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise. At all relevant times, Defendants were "person" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, a legal or beneficial interest in property.

207. For over a decade, the Defendants aggressively sought to bolster their revenue, increase profit and grow their share of the prescription opioid market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of opioids. As "registrants," the Defendants operated and continue to operate within the closed system created by the CSA. The CSA restricts the Defendants' ability to manufacture or distribute Schedule II controlled substances like opioids by requiring Defendants to maintain effective controls against diversion, design and operate a

system to identify suspicious orders and halt such unlawful sales and report them to the DEA, and to make sales within a limited quota set by the DEA.

208. The closed system created by the CSA, including the establishment of quotas, was specifically intended to reduce or eliminate the diversion of Schedule II controlled substances, including opioids.

209. Finding it impossible to achieve their increasing sales ambitions through legal means, the Defendants systematically and fraudulently violated their statutory duties to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders and to notify the DEA of suspicious orders. The Defendants repeatedly engaged in unlawful sales of opioids, which, in turn, artificially and illegally increased the annual product quotas for opioids allowed by the DEA.

210. An association-in-fact enterprise between the Distributor Defendants and the Pharmaceutical Defendants hatched this illegal scheme, and each Defendant participated in the scheme's execution, the purpose of which was to engage in the unlawful sale of opioids while deceiving the public and regulators into believing that the Defendants were faithfully fulfilling their obligations. As a direct result of the Defendants' scheme, they were able to extract billions of dollars in revenue while entities like the Ponca Tribe experienced an enormous amount of money in injuries caused by the foreseeable—and inevitable—consequences of the opioid epidemic Defendants created.

211. Alternatively, Defendants were also members of a legal entity enterprise. The Healthcare Distribution Alliance ("HDA")[55] is a distinct legal entity that qualifies as an enterprise under 18 U.S.C. § 1961(4). On information and belief, each Defendant is a member, participant, and/or sponsor of the HDA. Defendants utilized the HDA to conduct the RICO Enterprise. Each of the Defendants is a legal entity separate from the HDA.

212. The RICO Enterprise: Congress enacted the CSA to create a closed system for distribution of controlled substances. Congress was concerned with the diversion of drugs out of legitimate channels of distribution. Moreover, Congress specifically designed the closed system to ensure that there are multiple ways of identifying and preventing diversion.

213. A central component of the closed system was Congress's directive that the DEA determine quotas of each basic class of Schedule I and Schedule II controlled substances each year.

214. The Defendants operated as an association-in-fact to unlawfully increase sales and revenues in order to unlawfully increase the quotas set by the DEA, which in turn allowed them to collectively profit from distributing a greater pool of opioids each year. Each member of the Rico Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding profits generated by the scheme.

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[55] Health Distribution Alliance, *History*, Health Distribution Alliance, https://www.healthcaredistribution.org/about/hda-history (last accessed December 21, 2017).

215. The Defendants also engaged in lobbying efforts against the DEA's authority to investigate and hold responsible those who failed in their duty to prevent diversion. The Ensuring Patient Access and Effective Drug Enforcement Act was the result of an effort by the Defendants to reduce the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations. On information and belief, the Pain Care Forum and its members poured millions of dollars into lobbying efforts while the HDA devoted over a million dollars a year to lobbying.

216. The RICO Enterprise functioned by selling prescription opioids in interstate commerce in violation of the Defendants' legal obligations to maintain effective controls against opioid diversion.

217. Each Defendant communicated with other Defendants, shared information on a regular basis, and participated in joint lobbying efforts, trade industry organizations, contractual relationships, and other coordination of activities to effect the RICO Scheme. The contractual relationships included, on information and belief, rebates and/or chargebacks on opioid sales and security arrangements. All told, from 2006 to 2015, the Defendants worked together through the Pain Care Forum to spend over $740 million in lobbying across the country to enable the RICO enterprise.[56]

[56] *See* Matthew Perrone, *Pro-Painkiller echo chamber shaped policy amid drug epidemic*, The Center for Public Integrity, https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber- shaped-policy-amid-drug-epidemic (last accessed December 21, 2017).

218. The Defendants disseminated false and misleading statements to the public regarding the safety of prescription opioids for chronic pain relief. The Defendants also falsely disseminated statements that they were complying with their obligations to maintain effective controls against the diversion of their prescription opioids.

219. The Defendants refused to identify, investigate, or report suspicious orders despite their actual knowledge of drug diversion rings.

220. The Defendants worked together to ensure that opioid production quotas continued to increase, allowing them to generate more and more profits from the RICO Enterprise.

221. The RICO Scheme participants took intentional and affirmative steps to conceal the Scheme, including by using unbranded advertisement, third parties, and the Front Groups to disguise the source of the participants' fraudulent statements and to increase the effectiveness of the participants' misinformation campaign. These actions were taken to ensure that the RICO Scheme continued to be effective.

222. The pattern of racketeering activity. Each time that a participant in the RICO Scheme distributed a false statement by mail or wire, it committed a separate act of mail fraud or wire fraud under 18 U.S.C. §§ 1341 and 1341, respectively.

223. The Defendants used, or caused to be used, thousands of interstate mail and wire communications through virtually uniform misrepresentations, concealments, and material omissions regarding the safety of opioids and their compliance with the CSA's anti-diversion requirements. The Defendants committed this continuous pattern of

racketeering activity intentionally and knowingly with the intent to advance the RICO Enterprise.

224. The Defendants also conducted a pattern of racketeering by the felonious manufacture, importation, receiving, concealment, buying, selling or otherwise dealing in a controlled substance punishable under any law of the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false information or omit any material information from any application, report, record or other document required to be made, kept, or filed, a violation of which is a felony.

225. Each of the Defendants was a registrant under the CSA and was required to maintain effective diversion controls and investigate and report suspicious orders. The Defendants knowingly and routinely furnished false, misleading, or incomplete information in their reports to the DEA and in their applications for production quotas.

226. As described herein, the Defendants did unlawfully, knowingly, and intentionally conspire, confederate, and agree with each other to engage in the scheme described herein, in violation of 18 U.S.C. § 1962(c) and (d).

227. As a result of the conduct by the Defendants, the Ponca Tribe has been and will continue to be injured in an amount to be determined in this litigation.

228. Pursuant to 18 U.S.C. § 1964(c), the Ponca Tribe is entitled to recover threefold their damages, costs, and attorney's fees. In addition, the Ponca Tribe is entitled to injunctive relief to enjoin the racketeering activity.

COUNT II: LANHAM ACT, 15 U.S.C. § 1125(a)(1)(B)

229. The Ponca Tribe incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

230. The Lanham Act provides, in pertinent part:

> (A) Any person who, on or in connection with any good or services, or any container for goods, uses in commerce any word, terms, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of what, which –
>
> (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person how believes that he or she is or is likely to be damaged by such act.

231. As alleged in this Complaint, the Pharmaceutical Defendants committed repeated and willful unfair and/or deceptive acts or practices, and unconscionable trade practices, in connection with the sale of goods or services.

232. The Pharmaceutical Defendants engaged in a false and misleading advertising campaign designed to deceive doctors and the public into believing that opioids were safe for the treatment of chronic pain.

233. The Ponca Tribe is entitled to legal and equitable relief, including injunctive relief, disgorgement of profits, and damages in an amount to be determined in this litigation.

COUNT III: OKLAHOMA CONSUMER PROTECTION ACTION, 15 O.S. §§ 751-65

234. The Ponca Tribe incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

235. The Ponca Tribe brings these claims against Defendants under Sections 761.1 of the Oklahoma Consumer Protection Act.

236. In carrying out their marketing campaigns described herein – including through advertising and sales calls – each Defendant violated the Oklahoma Consumer Protection Act.

237. Defendants engaged in "deceptive trade practices" as defined by the Oklahoma Consumer Protection Act because Defendants made misrepresentations and omissions in marketing their opioids that deceived or could reasonably be expected to deceive or mislead consumers.

238. Further, Defendants engaged in "unfair trade practices" as defined by the Oklahoma Consumer Protection Act because, as explained herein, Defendants' intentional practices of marketing their respective opioids so as to downplay their risks, overstate their efficacy, and misrepresent their medical necessity, including for off-label uses, constitute practices which offend established public policy and which are immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers.

239. Defendants knowingly made false or misleading representations as to the characteristics, ingredients, uses, and benefits of their respective opioids by downplaying

the risks of addiction and abuse, overstating the efficacy, and misrepresenting the medical necessity of their opioids.

240. Defendants knowingly misrepresented the state of the science and material facts regarding the addictiveness of their respective opioids.

241. Defendants knowingly omitted material information related to the addictiveness of their respective opioids.

242. Defendants knowingly misrepresented the efficacy of their respective opioids by marketing their opioids as improving function for patients for which there was no evidence to support these claims.

243. Defendants knowingly misrepresented the benefits and efficacy of their respective opioids by vastly overstating their ability to safely and effectively treat or manage pain on a long-term and/or short-term basis and omitting or downplaying the severe risk of addiction.

244. Defendants knowingly made false or misleading representations as to the source, sponsorship, approval, or certification of their respective opioids by downplaying the risks of addiction and abuse, overstating the efficacy, and misrepresenting the medical necessity of their opioids and propping up these false and misleading representations with additional false statements regarding certain academic reports and studies related to opioids.

245. Defendants also knowingly made false representations as to the sponsorship, approval, status, affiliation or connection of certain persons in the medical and academic communities with respect to their opioids.

246. Defendants misrepresented and/or omitted the results and conclusions of academic reports and studies related to the addictiveness, effectiveness, and medical necessity of their opioids.

247. Defendants made false representations and/or omissions as to the sponsorship, approval, and/or certification by the medical professionals who performed or authored these academic reports and studies, which Defendants misused in their marketing efforts.

248. Defendants made false representations and/or omissions as to the sponsorship, approval, and/or certification by the journals that published these academic reports and studies, which Defendants misused in their marketing efforts.

249. Defendants misleadingly used these academic reports and studies to induce consumers, to prescribe, order, and/or purchase Defendants' opioids.

250. Defendants' misrepresentations caused actual damages to Plaintiff.

251. Pursuant to the Oklahoma Consumer Protect Act, Plaintiff seeks all available remedies appropriate relief, including an injunction against Defendants for its violations of the Act, actual damages and penalties allowable under the Act.

COUNT IV: PUBLIC NUISANCE, 50 O.S. § 2

252. The Ponca Tribe incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

253. Plaintiff brings this cause of action against Defendants to abate the public nuisance they created.

254. Defendants' misrepresentations and omissions regarding opioids, as set forth above, have created an opioid epidemic in Oklahoma and Plaintiff's community that constitutes a public nuisance. Defendants' acts and omissions created the opioid epidemic and thereby annoyed, injured, and endangered the comfort, repose, health and safety of others, including Plaintiff and its members.

255. Defendants' acts and omissions offend decency.

256. Defendants' acts and omissions render members of Plaintiff insecure.

257. Defendants' acts and omissions proximately caused injury to Plaintiff and its members, including, *inter alia*, recoupment of governmental costs, flowing from an ongoing and persistent public nuisance with the Ponca Tribe seeks to abate.

258. Defendants' acts and omissions affect the entire community of Plaintiff.

259. Defendants also have a duty to abate the nuisance caused the by prescription opioid epidemic.

260. Defendants have failed to abate the nuisance they created.

261. As a direct result of Defendants' conduct, Plaintiff and Plaintiff's community have suffered actual injury and economic damages including, but not limited to, significant expenses for police, emergency, health, prosecution, child protection, corrections and other services.

262. Defendants are liable to Plaintiff for the costs borne by Plaintiff as a result of the opioid epidemic and for the costs of abating the nuisance created by Defendants.

COUNT V: FRAUD

263. The Ponca Tribe incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

264. Defendants violated their general duty not to actively deceive and have made knowingly false statements and have omitted and/or concealed information which made statements Defendants did make knowingly false. Defendants acted intentionally and/or unlawfully.

265. As alleged herein, Defendants made false statements regarding their compliance with state, federal, and tribal law regarding their duties to prevent diversion, their duties to monitor, report and halt suspicious orders, and/or concealed their noncompliance with these requirements.

266. As alleged herein, the Pharmaceutical Defendants engaged in false representations and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain.

267. As alleged herein, Defendants knowingly and/or intentionally made representations that were false. Defendants had a duty to disclose material facts and concealed them. These false representations and concealed facts were material to the conduct and actions at issue. Defendants made these false representations and concealed facts with knowledge of the falsity of their representations and did so with the intent of misleading Plaintiff, Plaintiff's community, the public, and persons on whom Plaintiff relied.

268. These false representations and concealments were reasonably calculated to deceive Plaintiff, Plaintiff's community, and the physicians who prescribed opioids for persons in Plaintiff's community, were made with the intent to deceive, and did in fact deceive these persons, Plaintiff, and Plaintiff's community.

269. Plaintiff, Plaintiff's community, and the physicians who prescribed opioids reasonably relied on these false representations and concealments of material fact.

270. Plaintiff justifiably relied on Defendants' representations and/or concealments, both directly and indirectly. Plaintiff's injuries were proximately caused by this reliance.

271. The injuries alleged by Plaintiff herein were sustained as a direct and proximate cause of Defendants' fraudulent conduct.

272. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' fraudulent activity, including fraudulent misrepresentations and fraudulent concealment. Plaintiff does not seek damages for the wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by Defendants' actions.

273. Plaintiff seeks all legal and equitable relief as allowed by law, except as expressly disavowed herein, including inter alia injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

COUNT VI: UNJUST ENRICHMENT

274. The Ponca Tribe incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

275. Defendants received a benefit in the form of billions of dollars in revenue from the sale of prescription opioids to treat chronic pain.

276. Defendants were aware they were receiving that benefit. Defendants' conduct was designed to bring about that benefit.

277. Defendants retained that benefit at the expense of the Ponca Tribe, who has borne—and who continues to bear—the economic and social costs of Defendants' scheme.

278. It is inequitable for the Defendants to retain that benefit without paying for it.

279. Plaintiff is entitled to recover from Defendants' prescription opioid profits the amounts Plaintiff has spent and will have to spend in the future to address the effects of Defendants' actions.

COUNT VII: CIVIL CONSPIRACY

280. The Ponca Tribe incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

281. The Defendants agreed to engage in a campaign to flood the market with false and misleading information about the safety of prescription opioid use for the treatment of chronic pain, to evade controls on opioid diversion, and to increase opioid quotas.

282. The Defendants did so in an effort to profit off the increased sales of prescription opioids.

283. Each Defendant made false or misleading statements directly and through third parties to further the objectives of their conspiracy.

284. Plaintiff was directly and proximately harmed by the Defendants' civil conspiracy in an amount to be determined in this litigation.

COUNT VIII: NEGLIGENCE AND GROSS NEGLIGENCE

285. The Ponca Tribe incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

286. All Defendants had a legal duty to act with the exercise of ordinary care or skill to prevent injury to another under the common law and Oklahoma law.

287. All Defendants voluntarily undertook a legal duty to prevent the diversion of prescription opioids by engaging in the distribution of prescription opioids and by making public promises to prevent the diversion of prescription opioids.

288. All Defendants knew of the serious problem posed by prescription opioid diversion and were under a legal obligation to take reasonable steps to prevent diversion.

289. All Defendants knew of the highly addictive nature of prescription opioids and knew of the high likelihood of foreseeable harm to patients and communities, including Plaintiff, from prescription opioid diversion.

290. All Defendants breached their duties when they failed to act with reasonable care to prevent the diversion of prescription opioids.

291. Defendants' breaches of their duty of care foreseeably and proximately caused damage to Plaintiff.

292. Plaintiff is entitled to damages from Defendants in an amount to be determined in this litigation.

COUNT IX: NEGLIGENCE PER SE

293. The Ponca Tribe incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

294. All Defendants were obligated to prevent the diversion of prescription opioids under the CSA and its implementing regulations.

295. The CSA and its implementing regulations were enacted to promote safety and to prevent exactly the type of harm that occurred as a result of Defendants' failures.

296. All Defendants failed to perform their statutory and regulatory obligations under the CSA.

297. Oklahoma law prohibits engaging in misrepresentation or fraud in the distribution of a prescription drug.

298. This law was enacted to promote safety and prevent the type of harm that occurred as a result of Defendants' failures.

299. All Defendants engaged in misrepresentation and fraud, and aided and abetted the use of misrepresentation and fraud, in the distribution of prescription opioids in Oklahoma.

300. Defendants' breaches of their duty of care foreseeably and proximately caused damage to Plaintiff.

301. Plaintiff is entitled to damages from Defendants in an amount to be determined in this litigation.

COUNT X: PUNITIVE DAMAGES

302. The Ponca Tribe incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

303. By engaging in the above-described unfair acts or practices, Defendants acted with actual malice, wantonly, and oppressively. Defendants acted with conscious disregard to the rights of others and/or in a reckless, wanton, willful, or gross manner. Defendants acted with a prolonged indifference to the adverse consequences of their actions and/or omissions. Defendants acted with a conscious disregard for the rights and safety of others in a manner that had a great probability of causing substantial harm.

304. Here, Defendants were selling dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Thus, Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than legitimate medical, scientific, or industrial channels. Because of the severe level of danger posed by, and indeed visited upon Oklahoma and Plaintiff's community by, these dangerous drugs, Defendants owed a high duty of care to ensure that these drugs were only used for proper medical purposes. Defendants chose profit over prudence and the safety of the community, and an award of punitive damages is appropriate as a punishment and a deterrence.

305. By engaging in the above-described wrongful conduct, Defendants also engaged in willful misconduct and exhibited an entire want of care that would raise the presumption of a conscious indifference to consequences.

JURY TRIAL DEMAND

306. Plaintiff hereby requests a trial by jury.

RELIEF

WHEREFORE, the Plaintiff respectfully prays that this Court grant the following relief:

307. Entering Judgment in favor of the Plaintiff in a final order against each of the Defendants;

308. An award of all damages resulting from Defendants' violation of 18 U.S.C. § 1962(c) and (d), including prejudgment interest, the sum trebled pursuant to 18 U.S.C. § 1962(c);

309. Enjoining the Defendants and their employees, officers, directors, agents, successors, assignees, merged or acquired predecessors, parent or controlling entities, subsidiaries, and all other persons acting in concert or participation with it, from engaging in unfair or deceptive practices in violation of law and ordering temporary, preliminary, or permanent injunction;

310. Ordering that Defendants compensate the Plaintiff for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;

311. Ordering Defendants to fund an "abatement fund" for the purposes of abating the opioid nuisance;

312. Awarding actual damages, treble damages, punitive damages, injunctive and equitable relief, forfeiture as deemed proper by the Court, and attorney fees and all costs and expenses of suit pursuant to Plaintiff's racketeering claims;

313. Awarding the Plaintiff the damages caused by the opioid epidemic, including (A) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (B) costs for providing treatment, counseling, and rehabilitation services; (C) costs for providing treatment of infants born with opioid-related medical conditions; (D) costs for providing care for children whose parents suffer from opioid-related disability or incapacitation; and (E) costs associated with law enforcement and public safety relating to the opioid epidemic.

314. Awarding judgment against the Defendants requiring Defendants to pay punitive damages;

315. Granting the Plaintiff the cost of investigation, reasonable attorneys' fees, and all costs and expenses; pre-judgment and post-judgment interest; and,

316. All other relief as provided by law and/or as the Court deems appropriate and just.

Respectfully Submitted,

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